

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

	)
IN RE: AREDIA AND ZOMETA	)
PRODUCTS LIABILITY LITIGATION	) NO. 3:06-MD-1760
	) JUDGE CAMPBELL
This Document Relates to Case	)
No. 3:06-0381 (Hogan )	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 2262).

For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part.

FACTS

Plaintiff is the surviving widow of Timothy Hogan and alleges that Defendant's product Zometa caused Mr. Hogan to develop osteonecrosis of the jaw ("ONJ"). Plaintiff asserts causes of action for design defect, failure to warn, breach of express warranty, and breach of implied warranty. Defendant has moved for summary judgment on all of Plaintiff's claims.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). In order to defeat a summary judgment motion, the nonmoving party must provide more than a scintilla of evidence; that is, the nonmoving party must present

evidence sufficient to permit a reasonable jury to find in its favor. *Van Gorder*, 509 F.3d at 268. Entry of summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's cases, and on which that party will bear the burden of proof at trial. *Id.*

## CAUSATION

Defendant first asserts that Plaintiff has no admissible expert testimony on general causation for the reasons stated in Defendant's Motion for Summary Judgment Based on Failure of General Causation Proof under *Daubert*. The Court has denied that motion.

Defendant also asserts that Plaintiff has no admissible proof of specific medical causation because the Court should exclude the case-specific causation opinions of Plaintiff's retained expert Dr. Marx and any case-specific causation opinions of Mr. Hogan's treating physicians designated as non-retained experts. The Court has not considered the specific causation testimony of Plaintiff's non-retained experts in this case. The Court is denying Defendant's Motion to Exclude the Testimony of Dr. Marx, however.

Under Rhode Island law, which must be applied in this case, in order to prove proximate cause, Plaintiff must prove by a preponderance of the evidence that but for Defendant's alleged misconduct, Mr. Hogan's ONJ injury would not have occurred. *DiPetrillo v. Dow Chemical Co.*, 729 A.2d 677, 692 (R.I. 1999).

Dr. Marx testified at his March 6, 2009 deposition that Mr. Hogan had ONJ caused by Zometa. Docket No. 2685-4, pp. 1262, 1265-66. Defendant argues that this opinion goes beyond Dr. Marx's Original and Rebuttal Reports which merely stated that Mr. Hogan did not have multiple myeloma. Defendant contends that Dr. Marx's opinion at the March 6th deposition, which is

restated in his Declaration of June 24, 2009, at paragraphs 13 and 18, is a “new” opinion and was untimely disclosed.

The Court finds that Dr. Marx’s opinion concerning the cause of Mr. Hogan’s ONJ was not a completely new opinion and that Defendant was not prejudiced in the timing of its disclosure because Defendant had full opportunity to question Dr. Marx about it at his March 6, 2009 deposition. In addition, the records reflect that Dr. Marx did not receive Mr. Hogan’s actual pathology slides, which he used to confirm his opinion that Mr. Hogan suffered from bisphosphonate-induced ONJ, until June 18, 2009. Marx Declaration dated June 24, 2009, ¶¶18-20.

Defendant’s arguments related to the supplementation of Dr. Marx’s opinions concerning Mr. Hogan may be used on cross-examination to discredit his testimony. But, for purposes of summary judgment, the Court has considered Dr. Marx’s testimony concerning the specific causation of Mr. Hogan’s ONJ and finds that Plaintiff has carried her burden to show that there are genuine issues of material fact as to whether Zometa caused Mr. Hogan’s ONJ.

#### FAILURE TO WARN

Defendant argues first that its warnings were adequate as a matter of law. For the reasons the Court denied Defendant’s Motion for Summary Judgment on the Adequacy of Warnings, this argument fails. There are genuine issues of material fact as to what Defendant knew or should have known when and what warnings would have been reasonably adequate at the time.

Defendant also argues that Plaintiff cannot prove that different warnings would have made a difference in Mr. Hogan’s development of ONJ. Whether different warnings would have caused Mr. Hogan’s treating physicians and/or Mr. Hogan to behave differently and whether that different

behavior would have prevented his ONJ involve genuine issues of material fact which preclude summary judgment on this issue. There is an issue of fact as to what the oncologist knew at the times he continued Mr. Hogan's Zometa therapy. There are questions as to whether Mr. Hogan would have objected to Zometa had he received additional warnings from his treating physicians. There are issues as to what, if anything, Mr. Hogan's dentist and oral surgeon would have done differently had different warnings been given by Defendant.

Given additional knowledge, Plaintiff's oncologist might have still prescribed the drug, but Plaintiff himself and/or Plaintiff's dentist or oral surgeon might have behaved differently. For purposes of summary judgment, there are genuine issues of material fact as to whether different warnings would have made a difference in either the onset or the extent of Mr. Hogan's ONJ.

#### DESIGN DEFECT

Rhode Island recognizes a cause of action for personal injuries caused by prescription drugs based on a theory of strict liability in tort. *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 779 (R.I. 1988). The concept of strict liability in tort contemplates that there must be a defect in the design or manufacture that makes the product unsafe for its intended use. *Id.* The Rhode Island Supreme Court has extended strict liability to cover cases in which the manufacturer failed to warn of its product's dangerous propensity. *Id.*

Defendant contends that it is entitled to protection under Comment k to the Restatement (Second) of Torts, § 402A, which recognizes that certain products have dangers associated with their use even though they are manufactured and used as intended. It provides that those products that are deemed "unavoidably safe" should be exempted from the no-fault strict liability analysis of Restatement (Second) of Torts, § 402A. This comment provides a risk-benefit test for products that,

given the present state of human knowledge, are incapable of being made safe for their intended use. Their known or perceived benefits exceed their known or perceived risks. *Castrignano*, 546 A.2d at 779-80. If a product falls within comment k, then the defense is that such a product, properly prepared, and accompanied by proper directions and warnings, is not defective nor is it unreasonably dangerous. *Id.* at 780.

Determining whether Defendant is entitled to the protections of Comment k requires a risk-benefits analysis which involves questions of fact much like the issues underlying the failure to warn claim. In addition, comment k protects only those products which are accompanied by proper directions and warnings, and there are genuine issues of material fact as to whether Zometa was so accompanied. Thus, Plaintiff's design defect claim involves numerous issues of fact which preclude summary judgment, as the Court must look at the reasonableness of Defendant's behavior, the warnings which were given, and also the required element of causation.

#### EXPRESS WARRANTY

Under Rhode Island law, express warranties are governed by statute. RI. Gen. Laws, § 6A-2-313. The plaintiff who claims breach of express warranty has the burden of proving that the statements or representations made by the seller induced her to purchase the product and that she relied upon such statements or representations. *Thomas v. Amway Corp.*, 488 A.2d 716, 720 (R. I. 1985). An "express warranty" includes any affirmation of fact or promise made by the seller to the buyer which becomes part of the basis of the bargain and any description of the goods which is made part of the basis of the bargain. RI. Gen. Laws, § 6A-2-313.

Plaintiff avers that Defendant made certain false and misleading statements in its "Dear Doctor" letter which constituted an express warranty. The Court disagrees that such statements rise

to the level of “express warranty” under Rhode Island law. In addition, the Plaintiff has failed to carry her burden of showing that any alleged affirmation of fact, promise, or description made by Novartis induced Mr. Hogan or his treating physicians to purchase Zometa.

Therefore, Defendant’s Motion for Summary Judgment on Plaintiff’s express warranty claim is granted, and that claim is dismissed.

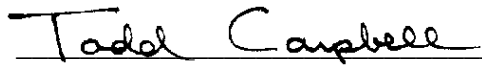
#### IMPLIED WARRANTY

Under Rhode Island law, there exists an implied warranty of merchantability of goods. R.I. Gen. Laws, § 6A-2-314. To be “merchantable,” the goods must, among other things, be adequately contained, packaged, and labeled. *Id.* For the same reasons there are issues of fact as to Plaintiff’s failure to warn claim, there are issues of fact as to whether Defendant’s product was adequately contained, packaged and labeled.

#### CONCLUSION

For all these reasons, Defendant’s Motion for Summary Judgment (Docket No. 2262) is GRANTED in part and DENIED in part. Plaintiff’s breach of express warranty claim is DISMISSED.

IT IS SO ORDERED.

  
TODD J. CAMPBELL  
UNITED STATES DISTRICT JUDGE